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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,923	10/21/2005	Catherine Allieux	124-000610US	1226
22798 7590 03/23/2009 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501				
EXAMINER CHEU, CHANGHWAI				
ART UNIT		PAPER NUMBER		
1641				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/553,923

Applicant(s)

ALLIOUX ET AL.

Examiner

JACOB CHEU

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 5, 7-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-5, 7-18 and 20-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.
2. Applicant's amendment filed on 12/24/2008 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

Claims 3, 6, 19 and 22-23 had been cancelled.

Claims 1-2, 4-5, 7-18 and 20-21 are under examination.

3. The instant case has been transferred to Examiner Jacob Cheu for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-5, 10, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al. (Analytical Chem. 1995, Vol. 67 page 1153-1158).

With respect to claims 1, 5, 10 and 15-17, Nelson et al. teach a method of determining host cell proteins in a sample. Nelson et al.

Teach immobilizing a mixture of biospecific affinity reagents, i.e. polyclonal antibodies specific for cell proteins, onto a protein biochip (See Experimental Section, page 1154).

Nelson et al. teach applying biological samples containing target proteins unto the biochip and detecting the captured proteins by matrix assisted laser mass spectrometry to produce a mass spectrum comprising molecular masses of the captured proteins or ionized fragments to analyze the host proteins in the sample (See Figure 1 and Figure 2).

With respect to claim 2, the samples are from biological fluid, e.g. blood (See Experimental Section).

With respect to claim 4, the affinity reagents used by Nelson et al. are IgG immunoglobulins. Supra.

With respect to claim 18, Nelson et al. also teach using protein A as capturing molecule (See Figure 1).

6. Claims 1-2, 4-5, 7-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutchens et al. (US 20010014461).

With respect to claims 1, 5, 7-9, 12 and 15-17, Hutchens et al. teach a method of determining host cell proteins in a sample. Hutchens et al. teach immobilizing a mixture of biospecific affinity reagents, i.e. polyclonal antibodies specific for cell proteins, onto a protein biochip (See Figures 14-15; Section 0140 for polyclonal antibodies Hutchens et al. teach applying biological samples containing target proteins unto the biochip and detecting the captured proteins by matrix assisted enhanced surface laser mass spectrometry to produce a mass spectrum comprising molecular masses of the captured proteins or ionized fragments to analyze the host proteins in the sample (See Figure 1 and Figure 2; 0109, 0114, 141, 173, 178, 201 for washing and eluting).

With respect to claim 2, the samples are from biological fluid, e.g. blood, organ lysate, (See Section 0129).

With respect to claim 4, the affinity reagents used by Hutchens et al. are IgG immunoglobulins (See Section 0206).

With respect to claims 10-11, the matrix can be organ polymer derivatives (See Section 0147).

With respect to claims 14, 18, Hutchens et al. also teach using protein A as capturing molecule (See Section 229 and 345).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al.,

Hutchens et al. reference has been discussed above, and Hutchens et al. teach applying the method for purification strategy (See Section 0270, 0290 and 0291). Hutchens et al.

also teach using recombinant techniques for producing interested target polypeptides (See 145, 218, 219, 329). However, Hutchens et al. do not explicitly teach exact same steps recited in claim 20 for purification. Nevertheless, it would have been prima facie to one ordinary skill in the art at the time the invention was made to have motivated Hutchens et al. to first profiling a sample as has been shown in claim 1, e.g. mass spectrum data for targeted proteins. Then, use the set of data as a comparison for subsequent purification. One ordinary skill would have further subjecting samples having potential target proteins with host proteins, e.g. blood samples having target proteins. One artisan would have also analyze the final product from purification process compared with the first stored profiling data.

Response to Applicant's Arguments

10. Applicant's arguments with respect to claims 1-2, 4-5, 7-18 and 20-21 have been considered but are moot in view of the new ground(s) of rejection.

11. It is noted that the original secondary reference Hutchens et al. is now used as 102 (b) anticipation reference. In view of the Remarks/Arguments, Applicant merely points out no motivation to combine Hutchen with Monforte and no reasonable expectation of success could have reached.

"Nor does Hutchens provide the motivation necessary to modify the Monforte methods to produce the claimed invention. Hutchens is only alleged to teach the advantages of SELDI over MALDI; the publication does not provide any motivation to modify the Monforte methods such that the Monforte signal polypeptide (essential to the cited advantages of performing the Monforte methods as compared to alternative detection methods) is no longer utilized. Furthermore, there is no motivation provided in either publication for one of skill in the art to perform the Monforte ELISA-style sandwich interaction in the presence of a SELDI matrix, given that the Monforte signal polypeptide must subsequently be generated (via retrieval of the expression cassette and expression of the encoded signal polypeptide)." (See page 8).

Examiner has withdrawn Monforte et al., and provides new evidence in establishing the anticipation of Hutchens et al. against this instant invention in this Office Action (See above).

12. **The following prior arts are not cited but are pertinent to this application.**

Merchant et al. Electrophoresis 2000 Vol. 21, page 1164-1169.

Xiao et al. Protein Expression and Purification 2000 Vol. 19, page 12-25.

US 6649358

US 6569383

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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